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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/534,825	03/23/00	FRUDAKIS	T 210121.419C7

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EXAMINER	
HARRIS, A	
ART UNIT	**PAPER NUMBER**
1642	9

DATE MAILED: 06/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/534,825	Frudakis et al.
Examiner	**Art Unit**
Alana M. Harris, Ph. D.	1642

-- The MAILING DATE of this communication app ars on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-60 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-60 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☒ Other: Restriction Election Facsimile Transmission

Election/Restriction

1. Prior to setting forth the Restriction Requirement, it is pointed out that applicants have presented the instant claims in improper format. The claims are improperly joined as the various groups indicated below appear to encompass numerous distinct nucleotides which encode myriad polypeptides to such an extent that they are considered separately patentable. A reference against one would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because these are not proper species. As noted in paragraph number upon election, applicant is required to point would which SEQ ID NO: sequences read upon the elected invention.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 17-20, drawn to an isolated polypeptide and a pharmaceutical composition and vaccine comprising said polypeptide, classified in class 530, subclass 350. Claims 17-20 will be examined with Group I to the extent that the pharmaceutical composition and vaccine comprise a polypeptide.

II. Claims 4-10 and 17-20, drawn to an isolated polynucleotide and a pharmaceutical composition and vaccine comprising said polynucleotide, classified in class 536, subclass 23.1. Claims 17-20 will be examined with Group II to the extent that the pharmaceutical composition and vaccine comprise a polynucleotide.

III. Claims 11, 17-20 and 54-57, drawn to an isolated antibody encoded by a polynucleotide sequence, a pharmaceutical composition, a vaccine and a diagnostic kit comprising said antibody, classified in class 530, subclass 387.1. Claims 17-20 will be examined with Group III to the extent that the pharmaceutical composition and vaccine comprise an antibody.

IV. Claims 12-15 and 17-20, drawn to a fusion protein, classified in class 530, subclass 350. Claims 17-20 will be examined with Group IV to the extent that the pharmaceutical composition and vaccine comprise a fusion protein.

V. Claims 16-20, drawn to an isolated polynucleotide encoding a fusion protein, classified in class 536, subclass 23.4. Claims 17-20 will be examined with Group V to the extent that the pharmaceutical composition and vaccine comprise a polynucleotide encoding a fusion protein.

VI. Claims 21, 22 and 31, drawn to a method for inhibiting the development of a cancer comprising administering a pharmaceutical composition or a vaccine comprising a polypeptide, classified in class 514, subclass 2. Claims 21, 22 and 31 will be examined with Group VI to the extent that the method comprising the administration of a polypeptide.

VII. Claims 21, 22 and 31, drawn to a method for inhibiting the development of a cancer comprising administering a pharmaceutical composition or a vaccine comprising a polynucleotide, classified in class 514, subclass 44. Claims 21, 22

and 31 will be examined with Group VII to the extent that the method comprising the administration of a polynucleotide.

VIII. Claims 21, 22 and 31, drawn to a method for inhibiting the development of a cancer comprising administering a pharmaceutical composition or a vaccine comprising an antibody, classified in class 424, subclass 130.1. Claims 21, 22 and 31 will be examined with Group VIII to the extent that the method comprising the administration of an antibody.

IX. Claims 21, 22 and 31, drawn to a method for inhibiting the development of a cancer comprising administering a pharmaceutical composition or a vaccine comprising a fusion protein, classified in class 514, subclass 2. Claims 21, 22 and 31 will be examined with Group IX to the extent that the method comprising the administration of a fusion protein.

X. Claims 21, 22 and 31, drawn to a method for inhibiting the development of a cancer comprising administering a pharmaceutical composition or a vaccine comprising a polynucleotide that encodes a fusion protein, classified in class 514, subclass 44. Claims 21, 22 and 31 will be examined with Group X to the extent that the method comprising the administration of a polynucleotide that encodes a fusion protein.

XI. Claims 23-31, drawn to a pharmaceutical composition and/or vaccine comprising an antigen-presenting cell, classified in class 435, subclass 325.

XII. Claims 32-34, drawn to a method for removing tumor cells comprising contact with T cells, classified in class 435, subclass 30.

XIII. Claim 35, drawn to a method for stimulating and/or expanding T cells, classified in class 436, subclass 8.

XIV. Claims 36, drawn to an isolated T cell population, classified in class 435, subclass 325.

XV. Claims 37-39, drawn to a method for inhibiting the development of a cancer comprising administering proliferated T cell, classified in class 424, subclass 9.1.

XVI. Claims 40-47, drawn to a method for determining the presence or absence of a cancer comprising the use of an antibody, classified in class 424, subclass 9.34.

XVII. Claims 48-53, drawn to a method for determining the presence or absence of a cancer comprising the use of an oligonucleotide, classified in class 435, subclass 6.

XVIII. Claims 58-60, drawn to an oligonucleotide and a diagnostic kit comprising the oligonucleotide, classified in class 536, subclass 22.1.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I-V, XI, XIV and XIII are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would

require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups VI-X, XII, XIII and XV-XVII differ in the method objectives, method steps and parameters and in the reagents used.

Inventions of Group I and of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I be used in *in vitro assays.*

Inventions of Group II and of Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group II be used in *in vitro assays.*

Inventions of Group III and of Groups VIII and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used in both methods of Groups VIII and XVI.

Inventions of Group IV and of Group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the fusion protein of Group IV be used in *in vitro assays.*

Inventions of Group V and of Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide encoding a fusion protein of Group V be used in *in vitro assays.*

Inventions of Group XIV and of Groups XI-XIII and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the T cell population of Group XIV can be used in all the methods of Groups XI-XIII and XV.

Inventions of Group XVII and of Groups II and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case both the products of Groups II and XVIII can be used in the method of Group XVII.

4. **With the election of any of Groups I-XVIII, the further election of <u>one</u> of SEQ ID NO:1, 3-26, 28-77, 142, 143, 146-152, 154-166, 168-176, 178-192, 194-198, 200-204, 206, 207, 207, 209-214, 216, 218, 219, 219, 221-240, 243-245, 247, 250, 251, 253, 255, 257-266, 268, 269, 271-273, 275, 276, 278, 280, 281, 284, 288, 291-298, 301-303, 307, 313, 314, 316 and 317. Additionally, with the election of Group I Applicant is requested to select the one amino acid sequence from SEQ ID NO: 299, 300, 304-306, 308 and 315 that corresponds with the selected nucleic acid.** Each of SEQ ID NO is a structurally and functionally different product, each encoding a structurally and functionally different product. The examination of all SEQ ID NO.s would require different searches in the U.S. Patent Shoes and the scientific literature.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Attempts to reach Gary M. Myles, Ph.D. by telephone on May 30, 2001 to request an oral election to the above restriction requirement were unsuccessful.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

8. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at Anthony.Caputa@uspto.gov or 703-308-3995. Thank you in advance for allowing us to enhance

our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

9. Papers related to this application may be submitted to Group 1642 by facsimile transmission. Papers should be faxed to Group 1642 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Sheela J. Huff

SHEELA HUFF
PRIMARY EXAMINER